PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Docket No: Q87778
Jaume Ribas PINOL, et al.	
Appln. No.: 10/535,416	Group Art Unit: 1645
Confirmation No.: 7473	Examiner: Khatol S SHAHNAN SHAH
Filed: May 19, 2005	

For: LIVE ATTENUATED VACCINE AGAINST PORCINE PLEUROPNEUMONIA"

STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the interview conducted on May 15, 2008:

REMARKS

An Examiner's Interview Summary Record (PTO-413) was mailed May 30, 2008.

During the interview, the following was discussed:

1. Brief description of exhibits or demonstration: None
2. Identification of claims discussed: All pending claims
3. Identification of art discussed: None
4. Identification of principal proposed amendments: See below
5. Brief Identification of principal arguments: See below
6. Indication of other pertinent matters discussed: See below

7. Results of Interview:

(1) With regard to the Restriction Requirement, Applicants' representatives requested withdrawal of the Restriction Requirement because the shared special technical features between Groups I-IV, i.e., an immunogenic and non-haemolytic *Actinobacillus pleuropneumoniae* (*App*) strain comprising at least one mutation in a transmembrane domain of the A gene for *apx*I and optionally at least one mutation in a transmembrance domain of the A gene for *apx*II, is not disclosed by Reimer et al. ((Microbial Pathogenesis 18: 197-209 (1995); "Reimer").

Applicants' representatives presented arguments to distinguish the claimed immunogenic, non-haemolytic APP strain over the mutant APP strains disclosed in Reimer. Specifically, Applicants' representatives explained that Reimer does not disclose a mutant strain which comprises a mutation in at least one region of the A gene for *apx*I and optionally a mutation in at least one region of the A gene for *apx*II. Instead, Reimer discloses a wildtype strain (J45) which synthesizes and secretes exotoxins ApxI and ApxII, a mutant with the C, B, A, and D genes (*apxICABD* operon) of ApxI completely deleted (mIT4-H), a mutant in which the deleted *apxICABD* operon is restored (MIT4-H/pJFF800), and a mutant in which the B and D genes (*apx*IBD operon) for ApxI is restored. It was suggested by Supervisory Patent Examiner Foley and Examiner Shahnan Shah that because it appears the claimed invention is directed to only a mutation in the A gene, it will be helpful to amend claim 13 to include a proviso that only the A gene is mutated. Supervisory Patent Examiner Foley and Examiner Shahnan Shah stated that such an amendment will be helpful in withdrawing the Restriction Requirement.

(2) With regard to the §101 rejection, Supervisory Patent Examiner Foley and Examiner Shahnan Shah agreed that amending the claims to recite "isolated" will overcome the rejection.

(3) With regard to the §112 rejection, Supervisory Patent Examiner Foley and Examiner Shahnan Shah agreed that providing a Rule 132 Declaration with data showing the efficacy of the claimed vaccine against a particular strain *Actinobacillus pleuropneumoniae* that causes porcine pleuropneumoniae will be helpful in addressing this rejection. In addition, it was suggested that amending claim 19 to clarify that the porcine pleuropneumoniae is caused by *Actinobacillus pleuropneumoniae* will be helpful in overcoming this rejection.

(4) With regard to the §102(b) rejections, Applicants' representatives presented arguments that neither MacInnes nor Prideaux discloses a mutation in at least one region of the *apx*IA and optional *apx*IIA gene.

Specifically, Applicants' representatives pointed out that MacInnes is directed to a method of preparing a vaccine in which the microorganism has at least one RTX toxin which is substantially cell-associated, but that such "substantially cell-associated" as defined at column 8 in MacInnes is not a mutation. Also, even though MacInnes discloses a modified App strain, only the B and D genes are modified (column 30 and claims 6-12 of MacInnes). In addition, Prideaux is directed to a modified App strain comprising an RTX A gene and an inactivated RTX C gene, so that only the C gene is mutated.

Supervisory Patent Examiner Foley indicated that such arguments will be helpful in overcoming the rejection.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

It is believed that no petition or fee is required. However, if the USPTO deems otherwise, Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,

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